Remarks

Claim 1 was amended to specify that the composition provides delayed and extended release of milnacipran to produce a therapeutic effect over approximately 24 hours when administered to a patient in need, with diminished incidence or reduced intensity relative side effects resulting from administration of the same dose of milnacipran administered in an immediate release formulation. Support for the amendment is found at least in claim 14 as originally filed and page 8, lines 30 to 31.

Claim 17 was amended to specify that less than approximately 20% of the total milnacipran dose is released in one hour when the formulation is subjected to *in vitro* dissolution in 0.1 N HCl. Support for the amendment is found at least in the Examples. New claims 29 was added specifying that less than approximately 20% of the total milnacipran dose is released in two hours when the formulation is subjected to *in vitro* dissolution in 0.1 N HCl. Support for the amendment is found at least in the Examples.

Claims 15 and 17 were amended to correct the dependency.

Claims 5, 6, 7, 9, 10, 13, and 14 were canceled. Claims 11, 16, 23, 25, and 26 were withdrawn.

Rejection Under 35 U.S.C. § 112, second paragraph

Claims 21, 22, and 24 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Applicants respectfully traverse this rejection to the extent that it is applied to the claims as amended.

Legal Standard

Exxon Research and Engineering Company v. United States , 265 F.3d 1371 (Fed. Cir. 2001), stated the standard to be as follows: "If one skilled in the art would understand the bounds of the claim when read in light of the specification, then the claim satisfies section 112 paragraph 2." *Id.* citing *Miles Labs, Inc., v. Shandon, Inc.*, 997 F.2d 870 (Fed. Cir. 1994). The court further stated that claims do not have to be plain on their face to be definite. Rather, "the claims need be amenable to construction, however difficult that task may be. If the meaning of the claim is discernible, even though the task may be formidable and the conclusion may be one over which reasonable persons will disagree, we have held the claim sufficiently clear to avoid invalidity on indefiniteness grounds." *Id.*

Analysis

The Examiner alleges that the phrases "therapeutically equivalent dose" and "dosage equivalent" are indefinite. Claims 21 and 22 have been amended to specify a therapeutically equivalent dose in order to be consistent with the language in claim 24. The Examiner alleges that the term "therapeutically equivalent dose" is not defined and it is unclear what is meant by the term. The Examiner is incorrect. The specification defines "milnacipran" to include pharmaceutically acceptable, pharmacologically active derivatives of milnacipran including both individual enantiomers of milnacipran, and their pharmaceutically acceptable salts, mixtures of the enantiomers and their salts, and active metabolites and their salts unless otherwise noted (page 10, lines 24-30). *It is understood that in some cases dosages of enantiomers, derivatives, and metabolites may need to be adjusted based on the relative activity of the racemic mixture of*

milnacipran (page 10, line 30 to page 11, line 2). This is due to the fact that one enantiomer is typically more reactive than the other and derivatives and/or metabolites have varying degrees of activity. Accordingly, the term "therapeutically equivalent dose" is definite, particularly when read in light of the specification.

The Examiner also alleges that the phrase "definite period of time" in claim 18 has no antecedent basis. Without making any admissions and solely for the purpose of facilitating prosecution, claim 18 has been amended to specify that the milnacipran is released over a period of time that is between approximately four hours and approximately twenty-four hours. Support for the amendment is found at least in claim 18 as originally filed and in the Examples.

Rejection Under 35 U.S.C. § 103

Claims 1-10, 12-15, 17, 18, and 27-28 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,980,882 to Eichman ("Eichman"). Claims 1-10, 12-15, 17, 18, 21, 22, 24, 27, and 28 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,980,882 to Eichman ("Eichman") in view of U.S. Patent No. 6,699,506 to Paillard *et al.* ("Paillard"). Claims 19 and 20 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,980,882 to Eichman ("Eichman") in view of U.S. Patent No. 6,699,506 to Paillard *et al.* ("Paillard") and further in view of U.S. Patent No. 6,602,911 to Kranzler *et al.* ("Kranzler"). Applicants respectfully traverse these rejections to the extent that it is applied to the claims as amended.

Analysis

1. Eichman

(a) Determining the scope and contents of the prior art

The scope and contents of the prior art must be analyzed *at the time the invention was made*. The requirement "at the time the invention was made" is to avoid impermissible hindsight. "It is difficult but necessary that the decision maker forget what he or she has been taught [...] about the claimed invention and cast the mind back to the time the invention was made (often as here many years), to occupy the mind of one skilled in the art who is presented only with the references, and who is normally guided by the then-accepted wisdom in the art." *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 U.S.P.Q. 303, 313 (Fed. Cir. 1983).

Eichman

Eichman describes a pharmaceutical composition comprising a drug-resin complex and a chelating agent in which the composition is in the form of a solid or a gel and methods of making thereof (abstract). Eichman discloses that the complex may be coated with a film-forming polymer (col. 12, lines 62 to 63). The coating can slow the rate of dissolution and slow the absorption of the drug in the GI tract (col. 12m lines 63-65). Eichman discloses that an enteric coating may be used if it is desirable for the complex to dissolve only in the intestine and not in the stomach (col. 12, lines 65-67). Eichman discloses that varying the amount of coating or combining coated with uncoated complexes in the same formulation can be used to adjust the dissolution profile as desired (col. 13, lines 14-16).

(b) Ascertaining the differences between the prior art and the claims

In determining the differences between the prior art and the claims, the question under 35 U.S.C. § 103 is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious. *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 218 USPQ 871 (Fed. Cir. 1983); *Schenck v. Nortron Corp.*, 713 F.2d 782, 218 U.S.P.Q. 698 (Fed. Cir. 1983).

The Claimed Compositions

The claimed compositions contain particles consisting of milnacipran complexed with an ion-exchange resin, wherein the composition provides delayed or extended release of milnacipran to produce a therapeutic effect over approximately 24 hours when administered to a patient in need, with diminished incidence or reduced intensity relative side effects resulting from administration of the same dose of milnacipran administered in an immediate release formulation. In one embodiment, the drug-resin particles are coated with an extended release coating and then with a delayed release coating (claims 7 and 8).

Eichman does not disclose or suggest a composition that provides delayed and extended release

In order to establish a *prima facie* case of obviousness, the references, alone or in combination, must disclose each and every element of the claims. Eichman discloses that drug-resin particles may be coated with an enteric coating so that the particles will dissolve in the intestine, not the stomach. Eichman does not disclose or suggest a composition that provides delayed and extended release as required by the claims. Further, Eichman does not disclose or

suggest a multiparticulate milnacipran composition provides delayed and extended release of milnacipran with diminished incidence or reduced intensity relative side effects resulting from administration of the same dose of milnacipran administered in an immediate release formulation. In fact, Eichman does not even mention side effects. Eichman is concerned with preparing formulations that are stable over an extended period of time, not minimizing side effects.

Merely stating that a drug can be administered using a sustained release formulation is not sufficient to establish that the formulation is effective to reduce side effects while still maintaining efficacy.

Table 1 in the present application shows that the incidence of certain adverse events associated with immediate release milnacipran formulations increases with dosage. As further shown in Table 1, a linear relationship does not exist between dosage and the incidence of the side effect. For example, the frequency of nausea decreased when increasing dosage from 50 mg/day twice daily to 100 mg/day twice daily, and then increased when increasing the dosage from 100 mg/day twice daily to 200 mg/day twice daily. The effect of the dose of milnacipran on the incidence and severity of side effects was not predictable at the time the present application was filed in view of this data. Only through a thorough understanding of the relationship between therapeutic dose and blood plasma levels can a modified dosage form be designed to reduce or diminish locally mediated side effects (page 7, lines 10-13).

The claimed compositions provide delayed and extended release of milnacipran to produce a therapeutic effect over approximately 24 hours when administered to a patient in need,

with diminished incidence or reduced intensity relative to one or more immediate release milnacipran side effects. Release of milnacipran is delayed until the formulation passes through the stomach thus minimizing locally mediated side effects. Extended release of milnacipran lowers the slope of the plasma curve and increases the T_{max} to effectively decrease centrally mediated side effects and provided for once-a-day administration of the drug. Eichman does not disclose each and every element of the claims. Further, it would not be obvious to replace the enteric coating of Eichman with the delayed and extended release coatings of the claimed compositions, particularly to reduce the incidence or intensity of milnacipran side effects in view of the fact that milnacipran induces both locally and centrally mediated side effects, which was not known at the time Eichman was filed. Therefore, claims 1-4, 7, 8, 12, 15, 17, 18, 27, and 38, as amended, are not obvious over Eichman.

2. Eichman in view of Paillard

(a) Determining the scope and contents of the prior art

Eichman is discussed above.

Paillard describes a pharmaceutical composition with *prolonged release* for oral administration of a single daily dose of milnacipran of 60 to 140 mg (abstract). The composition contains a plurality of microgranules each containing an active microsphere containing a saccharose and/or starch nucleus of a size between 200 and 2000 μm and containing 150 to 1000 μg of milnacipran and a binding agent (abstract). Each microgranule is coated with a film having a base of at least one polymer insoluble in water but permeable to physiological fluids of

a thickness between 20 and 100 µm (abstract). The composition has the following *in vitro* release profile: between 10 and 55% of the dose released in 2 hours; between 40 and 75% of the dose released in 4 hours; between 70 and 90% of the dose released in 8 hours; and between 80 and 100% of the dose released in 12 hours (abstract). *This release profile is achieved using only one type of microgranule per formulation* (col. 3, lines 20-25).

Paillard does not disclose or suggest a milnacipran formulation that provides delayed **and** extended release of milnacipran with diminished incidence or reduced the intensity of one or more immediate release milnacipran side effects. The coating agents used in Paillard are methacrylic acid copolymers of the poly(ethyl acrylate, methyl methacrylate) type in aqueous dispersion marketed under the name Eudragit NE30D, or of the poly(ethyl acrylate, methyl methacrylate, trimethylammoniumethyl methacrylate chloride) type in organic solvents (RS 100 or RL100) or in aqueous dispersion (RS30D/RL30D), whose permeability depends on the amount of ammonium groups (RL>RS) (col. 6, lines 52-58). Ethyl cellulose can also be used (col. 7, lines 1 to 2 and 10-13). As shown in the attached product descriptions and the article entitled "Guidelines for Formulation Development and Process Technology for Sustained Release Coatings" from the Degussa website, these polymers are extended or sustained release polymers, not delayed release polymers. For example, Eudragit RL, RS, and NE polymers are described as sustained release polymers in the document entitled "Acrylic Polymers for Controlled Release", a copy of which is enclosed. Accordingly, Paillard discloses compositions which provide extended release, not a mixture of delayed and extended release of milnacipran as required by the claims, as amended.

(b) Ascertaining the differences between the prior art and the claims

In determining the differences between the prior art and the claims, the question under 35 U.S.C. § 103 is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious. *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 218 USPQ 871 (Fed. Cir. 1983); *Schenck v. Nortron Corp.*, 713 F.2d 782, 218 U.S.P.Q. 698 (Fed. Cir. 1983). The claimed compositions are discussed above.

The references alone or in combination do not disclose each and every element of the claims

In order to establish a *prima facie* case of obviousness, the references, alone or in combination, must disclose each and every element of the claims. As discussed above, neither Eichman nor Paillard disclose or suggest a composition containing particles consisting of milnacipran complexed with an ion-exchange resin, wherein the composition provides delayed and extended release of milnacipran to produce a therapeutic effect over approximately 24 hours.

Eichman discloses that enteric coatings can be used so that the particles dissolve in the intestine, not the stomach. However, Eichman does not disclose compositions providing a combination of coatings, let alone a combination of delayed and extended release as required by the claims.

The formulations described in Paillard are extended release formulations as shown by the enclosed documents describing extended release polymers. Again, Paillard does not disclose or suggest a combination of release profiles, let alone a combination of delayed and extended release as required by the claims. The prolonged release characteristics of the formulations of

Paillard are imparted by coating minispheres of milnacipran with film-forming extended release polymers insoluble in water but permeable to physiologic fluids and which allows milnacipran in solution to pass through by diffusion phenomena (col. 6, lines 45-48). Many different types of coating polymers that provided extended release are disclosed (col. 6, line 49 – col. 7, line 6); however, Paillard does not disclose or suggest using any specific combinations of coatings, let alone a combination of extended release and delayed release as required by the claims. Paillard does not cure the deficiencies of Eichman.

Further, Eichman and Paillard fail to disclose or suggest a composition that provides delayed and extended release of milnacipran with diminished incidence or reduced intensity relative side effects resulting from administration of the same dose of milnacipran administered in an immediate release formulation. Merely stating that a drug can be administered using a sustained release formulation is not sufficient to establish that the formulation is effective to reduce side effects while still maintaining efficacy. The claimed compositions provide delayed and extended release of milnacipran. Release of milnacipran is delayed until the formulation passes through the stomach thus minimizing locally mediated side effects, while extended release of milnacipran lowers the slope of the plasma curve and increases the Tmax to effectively decrease centrally mediated side effects and provided for once-a-day administration of the drug. Neither Eichman nor Paillard disclose or suggest a formulation that reduces the frequency or diminishes the intensity of locally and centrally mediated side effects. The Examiner has failed to establish a *prima facie* case obviousness. Accordingly, claims 1-4, 7, 8, 12, 15, 17, 18, 21, 22, 24, 27, and 28, as amended, are not obvious over Eichman in view of Paillard.

3. Eichman and Paillard in view of Kranzler

(a) Determining the scope and contents of the prior art

Eichman and Paillard are discussed above.

Kranzler describes methods of treating fibromyalgia, chronic fatigue syndrome, and pain in an animal subject (abstract). The method involves administering a therapeutically effective amount of a dual serotonin norepinephrine reuptake inhibitor, such as milnacipran (abstract). Milnacipran can be administered adjunctively with other active compounds, including analgesics (col. 7, lines 55-57). Kranzler discloses that the dual serotonin norepinephrine reuptake inhibitor may be formulated for sustained release. As discussed above, sustained released is another term for extended or prolonged release. Kranzler does not disclose or suggest a formulation that provides delayed and extended release.

(b) Ascertaining the differences between the prior art and the claims

In determining the differences between the prior art and the claims, the question under 35 U.S.C. § 103 is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious. *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 218 USPQ 871 (Fed. Cir. 1983); *Schenck v. Nortron Corp.*, 713 F.2d 782, 218 U.S.P.Q. 698 (Fed. Cir. 1983). The claimed compositions are discussed above.

The references alone or in combination do not disclose each and every element of the claims

In order to establish a *prima facie* case of obviousness, the references, alone or in combination, must disclose each and every element of the claims. As discussed above, none of

the references discloses or suggests a composition containing particles consisting of milnacipran complexed with an ion-exchange resin, wherein the composition provides delayed and extended release of milnacipran to produce a therapeutic effect over approximately 24 hours. Eichman discloses that enteric coatings can be used if it is desirable for the complex to dissolve only in the intestine and not in the stomach. Paillard and Kranzler disclose extended or prolonged released compositions. None of the references disclose compositions that provide a combination of release profiles, let alone a combination delayed and extended release as required by the claims.

Further, Eichman, Paillard, and Kranzler, alone or in combination, fail to disclose or suggest a composition that provides delayed and extended release of milnacipran with diminished incidence or reduced intensity relative side effects resulting from administration of the same dose of milnacipran administered in an immediate release formulation. As discussed above, merely stating that a drug can be administered using a sustained release formulation is not sufficient to establish that the formulation is effective to reduce side effects while still maintaining efficacy. The claimed compositions provide delayed and extended release of milnacipran. Release of milnacipran is delayed until the formulation passes through the stomach thus minimizing locally mediated side effects, while extended release of milnacipran lowers the slope of the plasma curve and increases the Tmax to effectively decrease centrally mediated side effects and provided for once-a-day administration of the drug. None of the references cited disclose or suggest a formulation that reduces the frequency or diminishes the intensity of locally and centrally mediated side effects. The Examiner has failed to establish a *prima facie* case

obviousness. Accordingly, claims 1-4, 8, 12, 15, 17, 18, 21, 22, 24, 27, and 28, as amended, are not obvious over Eichman and Paillard in view of Kranzler.

Double Patenting Rejection

Claim 28 was provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 27 of copending Application Serial No. 11/192,697 in view of Eichman and Paillard.

Claims 1, 8, 13, 15, 20, 21, 22, and 24 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 9, 12, and 16-18 of copending Application Serial No. 10/690,872 in view of Eichman and Paillard.

Claim 27 was provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 24 of copending Application Serial No. 10/690,947 in view of Eichman and Paillard.

Applicants respectfully traverse these rejection.

Legal Standard

Before consideration can be given to the issue of double patenting, two or more patents or applications must have at least one common inventor and/or be either commonly assigned/owned or non-commonly assigned/owned but subject to a joint research agreement as set forth in 35 U.S.C. 103(c)(2) and (3) pursuant to the CREATE Act (Pub. L. 108-453, 118 Stat. 3596 (2004)). Congress recognized that the amendment to 35 U.S.C. 103(c) would result in situations in which there would be double patenting rejections between applications not owned by the same party (see H.R. Rep. No. 108-425, at 5-6 (2003)). For purposes of a double patenting analysis, the

application or patent and the subject matter disqualified under 35 U.S.C. 103(c) as amended by the CREATE Act will be treated as if commonly owned. See also MPEP § 804.03. Since the doctrine of double patenting seeks to avoid unjustly extending patent rights at the expense of the public, the focus of any double patenting analysis necessarily is on the claims in the multiple patents or patent applications involved in the analysis.

When considering whether the invention defined in a claim of an application would have been an obvious variation of the invention defined in the claim of a patent, the disclosure of the patent may not be used as prior art. *General Foods Corp. v. Studiengesellschaft Kohle mbH*, 972 F.2d 1272, 1279, 23 USPQ2d 1839, 1846 (Fed. Cir. 1992). This does not mean that one is precluded from all use of the patent disclosure. The specification can be used as a dictionary to learn the meaning of a term in the patent claim. *Toro Co. v. White Consol. Indus., Inc.*, 199 F.3d 1295, 1299, 53 USPQ2d 1065, 1067 (Fed. Cir. 1999).

Analysis

Claim 1 was amended to specify that the composition provides delayed and extended release of milnacipran. Claims 5, 6, 7, 9, 10, 13, and 14 were canceled. Claims 11, 16, 23, 25, and 26 were withdrawn.

The obviousness-type double patenting rejection of claim 28 over claims 27 of Application Serial No. 11/192,697 in view of Eichman and Paillard is legally incorrect

The Examiner alleges Eichman teaches methods of making a delayed release formulation of drug-ion exchange resin complexes that may be coated with an additional layer. The Examiner also alleges that Paillard teaches a delayed release milnacipran composition

comprising a saccharose core that can optionally be coated with another layer. The Examiner argues that one of ordinary skill in the art would be motivated to employ the method of making a drug resin complex of Eichman with the delayed release formulation of Paillard to arrive the method defined in claim 28. The Examiner's analysis is legally incorrect. As described above, in making a double patenting rejection, the disclosure of the patent may **not** be used as prior art. The Examiner makes no references to any claims in Eichman or Paillard, but rather summarizes what she believes each of the references teaches. The Examiner is attempting to use the references themselves as prior art in violation of the guidelines provided in the MPEP. This type of analysis is only appropriate under 35 U.S.C. 103 for obviousness, not for obviousness-type double patenting. Even if one could argue that such an analysis was proper, neither Eichman nor Paillard, alone or in combination, disclose or suggest a composition that provides delayed and extended release of milnacipran with reduced incidence or diminished intensity immediate release milnacipran side effects.

Moreover, the Examiner makes no mention of claim 27 of copending Application Serial No. 11/192,697, which allegedly is the basis for her rejection. Claim 27 defines a method of making a milnacipran formulation comprising providing a milnacipran formulation that provides **pulsatile** release of milnacipran to produce a therapeutic effect over approximately 24 hours when administered to a patient in need, with diminished incidence or reduced intensity of side effects resulting from administration of the same dose of milnacipran administered in an immediate release formulation. In contrast, claim 28 of the present application requires that the composition provide delayed and extended release.

A pulsatile release formulation is different than a formulation that provides delayed and extended release. A pulsatile release dosage form is one that mimics a multiple dosing profile without repeated dosing and allows at least a twofold reduction in dosing frequency as compared to that drug presented as a conventional dosage form (e.g. as a solution or prompt drug-releasing, conventional solid dosage form) (page 9, lines 5-11). A pulsatile release profile is characterized by a first dose of drug that is released substantially immediately following administration, followed by a period of no release followed by release of a first, and optionally a second, delayed release dose (page 9, lines 13-16). In contrast, a composition that provides delayed and extended release is characterized by a period of little or no release following administration and then extended release of the drug once the dosage form passes through the stomach into the intestines. A delayed and extended release formulation is not characterized by a first dose of drug that is released substantially immediately following administration, followed by a period of no release followed by release of a first, and optionally a second, delayed release dose. A combination of delayed and extended release is not obvious in view of a pulsatile release formulation. Accordingly, claim 28 is not obvious over claim 27 alone, or in combination with Eichman and Paillard.

The obviousness-type double patenting rejection of claims 1, 8, 13, 15, 20, 21, 22, and 24 over claims 1, 2, 9, 12, and 16-18 of Application Serial No. 11/690,872 in view of Eichman and Paillard is legally incorrect

The Examiner alleges Eichman teaches methods of making a delayed release formulation of drug-ion exchange resin complexes that may be coated with an additional layer. The Examiner also alleges that Paillard teaches a delayed release milnacipran composition comprising a saccharose core that can optionally be coated with another layer. The Examiner argues that one of ordinary skill in the art would be motivated to employ the method of making a drug resin complex of Eichman with the delayed release formulation of Paillard to prepare pulsatile release formulations. This rejection is unclear. The claims, as amended, define a composition the provides delayed and extended release of milnacipran with diminished incidence or reduced intensity of side effects resulting from administration of the same dose of milnacipran administered in an immediate release formulation. As discussed above, a combination of delayed and extended release is not an obvious variation of pulsatile release. Therefore, claims 1, 8, 13, 15, 20, 21, 22, and 24 are not obvious over Application Serial No. 10/690,872 in view of Eichman and Paillard.

Further, the Examiner's analysis is legally incorrect. As described above, in making a double patenting rejection, the disclosure of the patent may **not** be used as prior art. The Examiner makes no references to any claims in Eichman or Paillard, but rather summarizes what she believes each of the references teaches. The Examiner is attempting to use the references themselves as prior art. This type of analysis is only appropriate under 35 U.S.C. 103 for

obviousness, not for obviousness-type double patenting. Even if one could argue that such an analysis was proper, neither Eichman nor Paillard, alone or in combination, disclose or suggest a composition that provides delayed and extended release of milnacipran with reduced incidence or diminished intensity immediate release milnacipran side effects as required by the claims.

The obviousness-type double patenting rejection of claim 27 over claim 24 of Application Serial No. 10/694,947 in view of Eichman and Paillard is legally incorrect

For the reasons discussed above with respect to the double patenting rejections over Application Serial Nos. 11/192,697 and 10/690,872, the double patenting rejection of claim 27 is legally incorrect. Moreover, claim 27 requires milnacipran to be complexed to an ion-exchange resin in contrast to claim 24. Complexing a drug to an ion-exchange resin and then coating the resulting particles to provide delayed and extended release is not an obvious variation of claim 24 of Application Serial No. 10/694,947. Accordingly, claim 27 of the present application is not obvious over claim 24 of Application Serial No. 10/694,947.

The obviousness-type double patenting rejection of claims 1, 8, 15, 17, 18, and 20-22 over claims 1, 2, 4, 5, 9, 12, and 15-17 of Application Serial No. 10/691,936 in view of Eichman and Paillard is legally incorrect

For the reasons discussed above with respect to the double patenting rejections over Application Serial Nos. 11/192,697 and 10/690,872, the double patenting rejection of claims 1, 8, 15, 17, 18, and 20-22 is legally incorrect. Moreover, claims 1, 8, 15, 17, 18, and 20-22 require milnacipran to be complexed to an ion-exchange resin in contrast to claims 1, 2, 4, 5, 9, 12, and 15-17. Complexing a drug to an ion-exchange resin and then coating the resulting particles to

provide delayed and extended release is not an obvious variation of claims 1, 2, 4, 5, 9, 12, and 15-17 of Application Serial No. 10/691,936. Accordingly, claims 1, 8, 15, 17, 18, and 20-22 of the present application is not obvious over claims 1, 2, 4, 5, 9, 12, and 15-17 of Application Serial No. 10/691,936.

The obviousness-type double patenting rejection of claims 1, 8, 10, 15, 20, 21, and 24 over claims 1, 2, 9, 11, 14-16, 18, and 19 of Application Serial No. 10/192,885 in view of Eichman and Paillard is legally incorrect

For the reasons discussed above with respect to the double patenting rejections over Application Serial Nos. 11/192,697 and 10/690,872, the double patenting rejection of claims 1, 8, 10, 15, 20, 21, and 24 is legally incorrect. Moreover, claims 1, 8, 10, 15, 20, 21, and 24 require milnacipran to be complexed to an ion-exchange resin in contrast to claims 1, 2, 9, 11, 14-16, 18, and 19. Complexing a drug to an ion-exchange resin and then coating the resulting particles to provide delayed and extended release is not an obvious variation of claims 1, 2, 9, 11, 14-16, 18, and 19 of Application Serial No. 10/691,936. Accordingly, claims 1, 8, 10, 15, 20, 21, and 24 of the present application is not obvious over claims 1, 2, 9, 11, 14-16, 18, and 19 of Application Serial No. 10/192,885.

Allowance of claims 1-4, 8, 12, 15, 17-22, 24, 27, 28 and 29, as amended, is respectfully solicited.

Respectfully submitted,

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